

### **REMARKS**

The undersigned thanks Examiner Deo for the courtesies extended during the in-person interview along with inventor Christian Thonhauser at the USPTO on March 10, 2011. The content of the interview is discussed below.

Applicants respectfully request reconsideration of the present Application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1, 31 and 34 further recite “wherein concentrations of ingredients are such that the agent is pH buffered and storage-stable in liquid form.” Support for the amendments is found in U.S. Publication No. 20070102665 (which is the publication of the present specification) in paragraph [0009], which states that the claimed agent “in addition to the water-soluble permanganate, it comprises a further oxidation agent, whose oxidation potential is above that of manganese VII to manganese VI, pH buffer substances, preferably primary and/or secondary alkali carbonates, as well as oxidation-resistant polyphosphates. With the aid of this formulation it is possible to provide a storage-stable agent in liquid form.” [Emphasis added.] New claims 46-54 are copied from U.S. Patent No. 7,867,339. Support for these claims is provided below in a chart mapping the claims and the support. New claims 55-57 recite the claimed agent or aqueous solution containing the agent is configured to monitor color change. This limitation is supported by paragraph [0020] Example 1 of U.S. Publication No. 20070102665. No new matter has been added.

### **Claims rejections under 35 U.S.C. § 103**

The outstanding Official Action has rejected claims 1-5, 19, 20, 30-36, and 43 under 35 U.S.C. § 103 as allegedly being unpatentable over AT408987B (hereinafter AT), and further in view of RU 2191163 C1 (hereinafter RU).

The outstanding Office Action has rejected claims 6, 7, 30, and 39-42 under 35 U.S.C. § 103 as allegedly being unpatentable over AT/RU as applied to claims 1 and 9, and further in view of Wegner (U.S. Patent Publication No. 2003/0151024).

The outstanding Official Action has rejected claims 9-11, 13-15, 18, 22-29, 37, 38, 44, and 45 under 35 U.S.C. § 103 as allegedly being unpatentable over AT/RU as applied to claims 1 and 34 above, and further in view of admitted prior art.

These rejections are respectfully traversed.

During the interview, the Examiner asked Applicants to explain the deficiencies of AT and RU references as applied to the present invention. Applicants respectfully explained that the composition of AT is not pH buffered as it contains a large amount of NaOH. Therefore, the composition of AT is not storage-stable. Applicants also explained that the composition of RU contains organic matters (see abstract of RU) such that the permanganate would change color as and when the composition of RU is made. Therefore, the composition of RU would not function as an agent for monitoring the cleanliness of a plant by changing color upon reaction with organic substances in the plant. In short, irrespective of whether a person of ordinary skill would start with the composition of AT and combine with RU or start with the composition of RU and combine with AT, one would not arrive at the claimed agent "wherein concentrations of ingredients are such that the agent is pH buffered and storage-stable in liquid form" as recited in independent claims 1, 31 and 34.

The Examiner agreed that the proposed amendment would overcome the prior art rejections, but he said that he needs to consult with his SPE.

## **Declaration**

The outstanding Official Action indicates that the Declaration by co-inventor, Christian Thonhauser, filed February 2, 2011, is found to be unpersuasive for the alleged reasons cited therein.

During the interview, the undersigned asked the Examiner why he thought that the showing in the Declaration of February 2, 2011, was not commensurate with the scope of claims 1, 31 and 34. The Examiner said that he thought that the Declaration was not commensurate with the scope of claims 1, 31 and 34 as these claims did not state the concentrations of the ingredients that would allow the agent to be pH buffered and storage-stable in liquid form. The Examiner said that the proposed amendment to claims 1, 31 and 34 that the "concentrations of ingredients are such that the agent is pH buffered and storage-stable in liquid form" should overcome the objection that the Declaration of February 2, 2011, was not commensurate with the scope of claims 1, 31 and 34.

Finally, with respect to the Examiner's objection "that composition 1 [in the Declaration of February 2, 2011, which is the comparative composition by combining AT and RU] is storage-stable for sometimes before changing color" Applicants explained that the term "storage-stable" has an art recognized definition. As per the art recognized test of "storage-stable" as used by Applicants, the agent should be storage stable for at 40°C for 4 weeks of storage. As shown in the Declaration of February 2, 2011, composition 1 was not storage-stable while composition 2, an embodiment of the claimed agent, was indeed storage-stable. The Examiner suggested that Applicants should provide the art recognized definitions of the terms "pH buffer" and "storage-stable" such that the scope of claims 1, 31 and 34 are confined to agents "wherein concentrations of ingredients are such that the agent is pH buffered and storage-stable in liquid form." Applicants agreed.

As per OECD GUIDELINE FOR TESTING OF CHEMICALS, adopted 12 May 1981 (attached herewith), the accelerated storage test for a chemical to be storage-stable (i.e., stability) in air “calls for the controlled storage at 54°C to 55°C for 14 days and subsequent analysis.” See page 3, paragraph under “Accelerated storage test” in the attached OECD GUIDELINE FOR TESTING OF CHEMICALS. Alternatively, Applicants explained to the Examiner during the interview that one could do a storage test at a slightly lower temperature than 54°C to 55°C, i.e., at 40°C for a longer period than 14 days, i.e., 28 days, as was done in the tests shown in the Declaration of February 2, 2011.

The term “pH buffer” is generally referred in the art as either “chemical buffer” or “buffer solution.” “In general, chemical buffers are systems which, once constituted, tend to resist further change due to external influences.” McGraw-Hill Encyclopedia of Science and Technology, Vol. 2. page 475 (1982). “A buffer solution is one which resists changes in pH when small quantities of an acid or an alkali are added to it.” <http://www.chemguide.co.uk/physical/acidbaseeqia/buffers.html>

Finally, to completely address the objections raised by the Examiner regarding the Declaration of February 2, 2011, the undersigned asked the Examiner during the interview if Applicants should submit a supplementary declaration with any additional evidence to show that the objective evidence of nonobviousness is commensurate in scope with the claims. The Examiner said that Applicants do not need to provide any additional evidence once claims 1, 31 and 34 have been amended as herein, and the art recognized meanings of the terms “pH buffer” and “storage-stable” are provided by Applicants as done herein.

In light of the Examiner’s interview and the present Amendment, Applicants respectfully submit that claims 1, 31 and 34, and claims dependent from them should now be allowed.

## **Interference**

During the interview, Applicants also discussed about copying claims from U.S. Patent No. 7,867,339 (Fischer), which was granted on January 11, 2011, such that the Examiner might go ahead and declare an interference. New claims 46-54 are the same as claims 1-9 of Fischer. Support for new claims 46-54, which are claims 1-9 of Fischer, is found in U.S. Publication No. 20070102665 as follows:

<b>United States Patent</b>	<b>United States Patent Application Publication</b>
<b>US 7,867,339 B2</b>	<b>US 2007/0102665 A1</b>
<b>Fischer</b>	<b>Thonhauser</b>
<b>Title: Process for cleaning an installation</b>	<b>Title: Cleaning, disinfection and indicator agent</b>
<b>Claim 1: (numbered as per Fischer)</b>	
A process for the cleaning of an installation ...	Claim 9: A method for cleaning, disinfecting, and monitoring the cleanliness of commercial and industrial plants or plant components ...
... rinsing the installation with an alkaline cleaning solution ...	Claim 9: ... in aqueous solution with an agent for ensuring an alkaline milieu having a pH value of at least 11, preferably at least 12 ...
... testing the ... final cleaning result by using an indicator agent on the basis of permanganate in an alkaline environment	Claim 9: ... comprising a water-soluble permanganate, ... combined in aqueous solution with an agent for ensuring an alkaline milieu having a pH value of at least 11, preferably at least 12 ...
	Claim 16: A use of a solution made of a cleaning, disinfection, and indicator agent comprising a water-soluble permanganate ... and an agent for ensuring an alkaline milieu having a pH value of at least 11, preferably at least 12, as an indicator solution for ascertaining the cleanliness of commercial and industrial plants or plant components

... subsequently introducing the indicator agent that is used as an indicator into the alkaline cleaning solution for further use as a cleaning agent in a subsequent cleaning step.	[0053] ... an alkaline starting solution is provided in a tank from which a flow through the plant may be produced. During the circulation of this alkaline starting solution through the plant, the cleaning, disinfection, and indicator agent according to the present invention is admixed to the starting solution flowing out ...
	[0061] Since because of the yellowish color, cleanliness of the plant may not yet be discussed, 1% of the agent according to the present invention is again added to the tank.
	[0064] During the circulation of this starting solution (temperature 60° C), the cleaning, disinfection, and indicator agent according to the present invention is admixed in the solution flowing out.
<b>Claim 2, dependent from Claim 1:</b>	
... collecting the alkaline cleaning solution, after the cleaning run, in an alkaline solution container for reuse.	Not explicitly disclosed, but collecting the alkaline cleaning solution, after the cleaning run, in an alkaline solution container for reuse is a standard procedure in the industry.
<b>Claim 3, dependent from Claim 2:</b>	
... introducing the indicator agent used into the alkaline solution container.	Not explicitly disclosed, but implicit in the procedure disclosed in <b>US 2007/0102665 A1</b> , as has to be added to make up for the amount of indicator agent that has been consumed in the previous cleaning operation.
<b>Claim 4, dependent from Claim 1:</b>	
... introducing the indicator agent into the installation after the last cleaning step.	[0061] Since because of the yellowish color, cleanliness of the plant may not yet be discussed, 1% of the agent according to the present invention is again added to the tank.
<b>Claim 5, dependent from Claim 1:</b>	
... introducing the indicator agent into the installation before a sterilization step.	Not explicitly disclosed, but implicit in the procedure disclosed in <b>US 2007/0102665 A1</b> ; also, this limitation is obvious to persons skilled in the art since the introduction of an indicator agent after the sterilization step could render the installation unsterile.

<b>Claim 6, dependent from Claim 1:</b>	
... and determining a change brought about by the indicator agent by means of a monitoring device.	see support for disclosure in Fischer, Claim 7
<b>Claim 7, dependent from Claim 6:</b>	
... color value detector ...	[0054] ... The color value may again be ascertained with the aid of visual observation or mechanically and automatically with the aid of photometric in-line measurements.
	Claim 9: ... and the cleaning progress is tracked by ascertaining the intensity of the light emitted in the violet wavelength range by the solution.
	Claim 12: The method according to claim 11, wherein the cleaning progress is additionally tracked by ascertaining the intensity of the light emitted in the green and/or yellow wavelength ranges ...
	Claim 14: The method according to claim 9, wherein the light intensity is ascertained automatically.
<b>Claim 8, dependent from Claim 6:</b>	
... wherein the change brought about is a change in color.	[0004] ... As will be explained in greater detail, the dominance of a hexavalent manganese species present in the course of the cleaning progress results in a green coloration of the cleaning and disinfection agent, in contrast to the initially violet coloration, which is caused by manganese VII. A yellow coloration of the cleaning and disinfection agent, in contrast, indicates the presence of manganese (II) complexes and therefore also the almost complete consumption of the included oxidizing agent through strong organic impurities.

	[0036] ... for example, increased formation of manganese (VI) will occur. The dominance of the hexavalent manganese species results in a green coloration of the solution, in contrast to the initially violet coloration, which is caused by manganese VII.
	Claim 9: ...ascertaining the intensity of the light emitted in the violet wavelength range by the solution.
	Claim 10: ... ascertaining the intensity of the light emitted in the green and yellow wavelength ranges by the solution.
<b>Claim 9, dependent from Claim 1:</b>	
... locating the indicator agent inside a storage tank.	[0059] ... For this purpose, a volume of 6000 l of water is prepared in a tank (e.g., in the CIP tank) in the meaning of a "batchwise" (discontinuous) method. ... Directly before beginning the circulation, the cleaning, disinfection, and indicator agent according to the present invention is admixed in a concentration of 1%. Subsequently, a concentration of 0.50% is set with the aid of the lye (NaOH) ...



**CONCLUSION**

In view of the above amendment, applicant believes the pending application is in condition for allowance. The Director is authorized to charge any fees necessary and/or credit any overpayments to Deposit Account No. 03-3975, referencing Docket No. 085523-0381114.

Respectfully submitted,

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OECD GUIDELINE FOR TESTING OF CHEMICALS

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Adopted:  
12 May 1981

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**"Screening Test for Thermal Stability and Stability  
in Air"**

(Accelerated Storage Test [CIPAC-Test] - Thermal Analysis  
Methods, including differential thermal analysis [DTA] and  
thermogravimetric analysis [TGA])

**1. INTRODUCTORY INFORMATION**

• Guidance information

- Structural formula
- Vapour pressure curve
- Melting point
- Boiling point

• Qualifying statement

The test methods can be applied to pure and commercial grade substances. The potential effects of impurities on results must be considered.

• Standard documents

This Test Guideline is based on the

- CIPAC-recommendations (4) for stability testing of pesticides (short time storage test); and on
- consensus methods of thermal analysis (DTA, TGA).

**2. METHOD**

**A. INTRODUCTION, PURPOSE, SCOPE, RELEVANCE,  
APPLICATION AND LIMITS OF TEST**

The purpose of the methods is to obtain a preliminary judgement of the stability of a substance with respect to heat and air in order to provide guidance in the performance of other tests.

The methods for determining storage stability discussed in this Test Guideline are applicable to homogeneous solid and liquid substances and to mixtures of these.

Exothermic decomposition processes can be determined by differential thermal analysis (DTA). In order to determine endothermic effects it must be confirmed that it is a decomposition and no phase transition.

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*Users of this Test Guideline should consult the Preface,  
in particular paragraphs 3, 4, 7 and 8.*

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**"Screening Test for Thermal Stability and  
Stability in Air"**

The thermogravimetric analysis (TGA) determination gives information about decomposition reactions involving the elimination of volatile decomposition products.

With a TGA kinetic evaluation and extrapolation to lower temperatures may be easier than with DTA.

• Definitions and units (1.2.3)

- Thermal analysis (TA): General term describing analytical methods in which the changes in the physical parameters of a substance as a function of temperature are measured.
- Differential thermal analysis (DTA): Measurement of the temperature difference between a sample and the reference material as a function of time or temperature.
- Thermogravimetric analysis (TGA): Measurement of the weight change of a substance using an isothermal or anisothermal procedure as a function of time or temperature.
- Peak: The term "peak" describes the upward or downward deviation of the recording curve from the base line
- Peak temperature: Temperature at the peak maximum.

• Reference substances

Suitable reference substances are urea, 4-nitrophenol,  $\alpha$ -naphthylamine and naphthalene. These substances need not be employed in all cases when investigating a new substance. They are provided primarily so that calibration of the method may be performed from time to time and to offer the chance to compare the results when another method is applied.

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**"Screening Test for Thermal Stability and  
Stability in Air"**

• Principle of the test methods

Accelerated storage test (CIPAC)

A long duration storage instability can be simulated by applying a higher temperature during a short test. Such a "screening test" is described in the CIPAC - recommendations (4) for stability testing of pesticides. This test calls for the controlled storage at 54°C to 55°C for 14 days and subsequent analysis. In simple cases it will be enough to determine a characteristic property (e.g. melting point) before and after storage.

Thermal analysis methods

The sample and the standard reference material are heated up to the final temperature at a constant rate in a defined test atmosphere, either separately in a TGA or DTA apparatus or in a combined system, and the weight change of the sample or the quantities of heat absorbed or given off are measured and recorded. If, in the temperature range investigated, peaks are observed from which a chemical reaction of the sample can be deduced, the thermal analysis should be repeated in the immediate vicinity of the peak temperature.

• Quality criteria

Repeatability

DTA and TGA are well-known methods for determining thermal stability of chemical compounds. (See Section on accuracy, below).

Sensitivity

The sensitivity of the method is determined by the sensitivity of the measurement apparatus (equipment type) and the test conditions.

Possibility of standardisation

Standardisation of the test conditions for thermal analysis is described by McAdie (5).

Possibility of automation

There is some possibility for automation.

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**B. DESCRIPTION OF THE TEST PROCEDURES**

- Accelerated storage test  
(based on CIPAC - Test)

*Apparatus*

- Oven, thermostatically controlled
- Sample containers (250-ml beakers, glass bottles, sealable ampoules).

*Procedure*

Place 20 g of the sample in a bottle. If the substance is volatile place in a sealable ampoule. Water saturated air should be used as test atmosphere. Seal the sample container hermetically and keep it in the oven at  $55 \pm 2^\circ\text{C}$  for 14 days. Remove the sample container from the oven, cool down to room temperature, and determine by a suitable method (e.g. determination of melting point) whether decomposition or other chemical transformation has occurred.

- Differential thermal analysis (DTA) and  
differential scanning calorimetry (DSC)

*Apparatus*

DTA or DSC apparatus of commercially available type. (Block diagram of DTA apparatus: Figure 1).

Heat flow and energy compensated methods may both be applied. For volatile substances an apparatus should be available which allows measurements to be performed with closed sample containers or under elevated pressure.

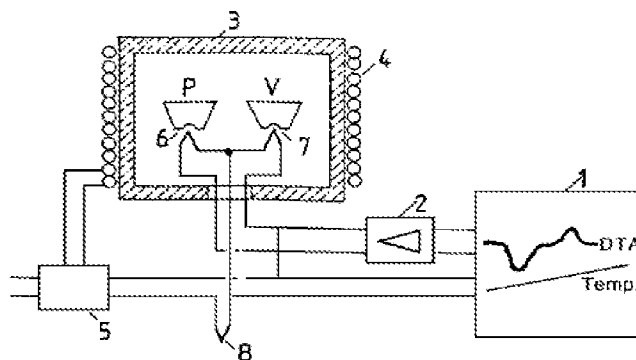
*Test conditions*

Sample containers of different kinds may be used: open or sealed glass tubes, metal pans, or pressure resistant crucibles. For measurements under oxygen-containing atmosphere only open sample containers are appropriate.

The test atmosphere is (a) nitrogen and (b) air. When air is used the sample is put in an open pan.

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*Figure 1: Block diagram of a DTA apparatus*



- 1 Two-channel recorder
- 2 D.C. amplifier
- 3 Furnace
- 4 Heater windings
- 5 Temperature regulator
- 6 Thermocouple with crucible P for sample substance
- 7 Thermocouple with crucible V for reference substance
- 8 Reference junction thermocouple

An inert reference substance is selected which undergoes no changes in the temperature region employed. Thermal conductivity and heat capacity of the inert reference sample should be nearly equal to those of the sample to be investigated. In many cases aluminium oxide is a useful inert substance.

**Procedure**

Samples of about 5 to 50 mg are weighed and closed in the sample container. The heating rate should be in the range of 2 to 20 K/min. At first a DTA diagram (for example see Figure 2) of the substance at normal pressure is recorded.

If a thermal effect (a peak) is found between room temperature and 150°C, one proceeds as follows:

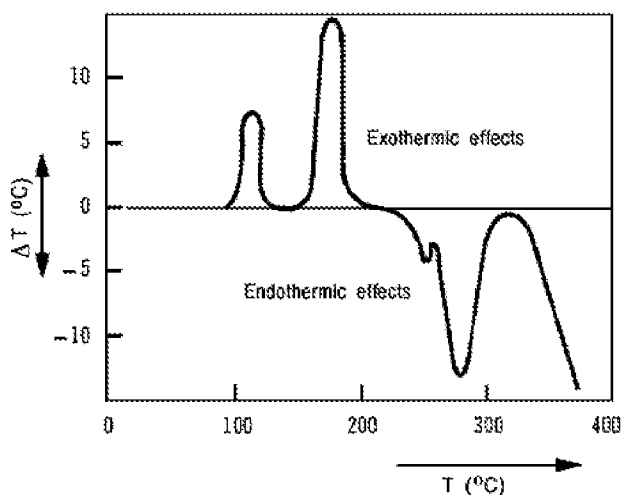
- (a) When the peak is due to an exothermic effect, it is assumed to be a decomposition.
- (b) When the peak is due to an endothermic effect, the temperature at which it occurs should be compared to the melting point of the substance.

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*Figure 2: DTA curve*



$T$  : temperature of the reference substance.  
 $\Delta T$  : temperature difference between sample and reference substance.

- (c) If the peak is due to an endothermic effect which is not related to the melting of the substance, the DTA should be repeated at a higher pressure (10-50 bar) or in a closed sample container. If the peak is shifted to a higher temperature, it comes from a vaporisation process.
- (d) If the endothermic effect is due neither to melting nor to vaporisation, repeated heating cycles are carried out around the peak temperature. If the peak does not persist a chemical transformation has occurred.

• Thermogravimetric analysis (TGA)

*Apparatus*

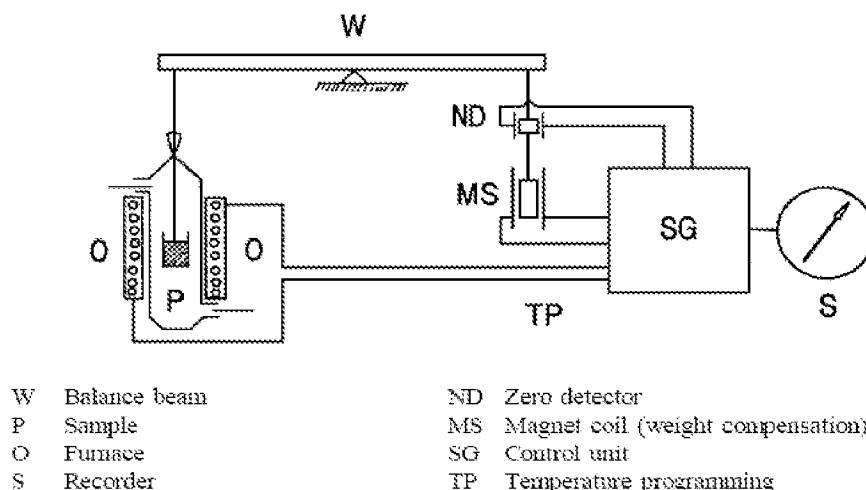
TGA Apparatus of common design, e.g. of commercially available type, allowing for heating the substance in air and in an inert atmosphere. (Diagrammatic sketch of the apparatus: Figure 3.)

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Figure 3: Diagrammatic structure of a TGA apparatus



### *Test conditions*

The test atmosphere is normally (a) nitrogen and (b) air. For testing oxidation stability air is used as atmosphere.

### *Procedure*

A sample of about 10 to 500 mg is heated in (a) nitrogen and (b) air, and the weight loss is recorded. The heating rate should be in the range of 2 to 20 K/min. A weight loss which does not originate from volatilisation of the substance is considered as a decomposition.

If a decomposition is observed at temperatures below 150°C the rate of decomposition can be determined by isothermic measurements.

## 3. DATA AND REPORTING

### • Interpretation of results

The substance is considered to be stable at room temperature if either



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- a) in the "Accelerated Storage Test (CIPAC-Test)" the melting point (or another characteristic property) has remained constant or if the content of original substance as determined by analysis has decreased by not more than 5 per cent

or

- b) in DTA or TGA no decomposition or chemical transformation is found below 150°C.

• Test report

The test report should contain the following information:

*Accelerated storage test*

- Type of sample container
- Method of determination of a chemical transformation
- Change of a typical property or percentage of decomposition after 14 days' storage.

*Thermal analysis*

- Type of apparatus employed
- Preliminary treatment and form of the sample
- Precise information on reference and test substances
- Temperature range investigated, rate of temperature increase, temperature specifications for isothermal procedure
- Quantity of substance
- Composition and purity of the test atmosphere
- Type of sample container
- Changes observed on the treated sample during and after testing
- Temperature of beginning chemical transformation
- Conditions deviating from this method
- Where possible, report nature of decomposition products.

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**4. L I T E R A T U R E**

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